DEPARTMENT OF HEALTH AND HUMAN SERVICES

M31287

Certified/Return Receipt Requested

U.S. Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
P.O. Box 15905
Lenexa, KS 66285-5905
Telephone: (913) 752-2100

November 3, 1999

WARNING LETTER

Michael E. DeDomenico
President and Chief Executive Officer
Praxair Distribution, Inc.
39 Old Ridgebury Road
Danbury, CT 06810-5113

KAN #2000-001

Dear Mr. DeDomenico:

Recently an inspection was made of your medical gas transfilling operation known as Praxair Distribution, Inc., 1700 2nd Avenue, Des Moines, Iowa. This inspection was conducted on August 16 and 20, 1999, by a Food and Drug Administration Investigator from this office who documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211). These deviations cause the medical gases transfilled at this location to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Significant deviations include, but are not limited to the following:

- Failure to produce batch production records for at least 9 lots of Liquid Nitrogen NF (LN) which were transfilled between 2-22-99 and 8-12-99.

- Failure to provide Certificates of Analysis on at least 5 containers of LN received between 3-26-99 and 7-13-99.

- Failure to perform an odor test of LN as required by your SOP POIS 2.510, Filling Open top Dewars and Flasks.

- Failure to calibrate the Servomex Oxygen Analyzer prior to use on 4-30-99 and 5-26-99, as required by your SOP POIS 6.5520.

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- Failure to make your SOPs readily available to employees performing transfilling operations of LN and Liquid Oxygen USP.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations, at each location operated by your firm. We are enclosing a copy of the Form FDA 483 that was issued to Ronnie W. Gillette, Supervisor, at the conclusion of the inspection.

We also received a letter dated September 12, 1999 from J.M. Hercik, Quality Assurance Manager, which is a response to the observations listed on the Form FDA 483. Mr. Hercik's letter was taken into consideration during the preparation of this letter. We will respond to Mr. Hercik by separate letter.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your liquid medical oxygen. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking, in addition to those outlined in Mr. Hercik's letter, to correct the problem. If you feel that Mr. Hercik's response of September 12 reflects your response to this letter, please let us know. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

Enclosure - Form FDA 483

cc: Bruce Gilbert, Division Operations Manager
Praxair Distribution, Inc.
1700 2nd Avenue
P.O. Box 188
Des Moines, IA 50301-0188